

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: Bair Hugger Forced Air Warming
Devices Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

This Document Relates to:
ALL CASES

**DEFENDANTS' RESPONSE TO
PLAINTIFFS' OBJECTION TO
MAGISTRATE JUDGE'S ORDER
BARRING PLAINTIFFS' NEW
GENERAL CAUSATION EXPERT
OPINIONS**

The Court should overrule Plaintiffs' objection to Judge Schultz's order excluding the expert report and opinions of Nathan Bushnell, and supplemental expert report and opinions of Yadin David.

As Judge Schultz correctly concluded in both his detailed oral ruling¹ and written order, Bushnell's 48-page report is an improper sur-rebuttal to the general causation rebuttal report of Defendants' CFD expert, Dr. John Abraham. Over a year ago, Plaintiffs requested leave of Court to serve a sur-rebuttal to Abraham's report, and the Court definitively denied that request. By now disclosing that sur-rebuttal, Plaintiffs flouted the Court's scheduling orders. Judge Schultz appropriately barred Plaintiffs from using Bushnell's opinions, as provided by Rules 16(f)(1)(C) and 37(b)(2)(A)(ii).

Judge Schultz also correctly concluded that David's supplemental general causation report improperly introduced major new alternative design opinions by proposing seven new patient warming products. (Order 5; 9/6/18 Tr. 57:2-20.) Rule 26(e) permits limited

¹ Judge Schultz gave a full explication of his decision at the hearing. The hearing transcript is Exhibit A to the accompanying Declaration of Benjamin W. Hulse.

supplementation to fill in gaps, correct errors, and address newly published studies. But the rule does not permit parties to expand their disclosures after the deadline by adding significant new opinions, especially when that bolstering is prejudicial to the other side. (Order 4-5; 9/6/18 Tr. 59:3-9.)

Here, Plaintiffs offered improper, prejudicial bolstering of David's opinions. David's seven new alternative designs all were available at the time of his original report. The supplementation was not harmless, as Defendants have had no opportunity to seek third-party fact discovery on David's newly identified products. Accordingly, Judge Schultz correctly barred Plaintiffs from using David's new opinions in any motion, hearing, or trial. Fed. R. Civ. P. 37(c)(1).

BACKGROUND

I. THE COURT BIFURCATED EXPERT DISCOVERY INTO TWO PHASES: GENERAL CAUSATION AND BELLWETHER CASE-SPECIFIC.

From the first scheduling order entered in the MDL, the Court bifurcated discovery into two phases: "general causation" and "bellwether case-specific" discovery. PTO 4. The parties and the Court have always understood "general causation" to mean discovery on general issues (not just causation) that are common to all or nearly all cases in the MDL. For example, under the heading of general causation, Plaintiffs served, and Defendants responded to, seven sets of requests for production on a wide range of cross-cutting issues, including alternative designs and regulatory compliance. (9/6/18 Tr. 51:13-24.) Under PTO 17, initial expert reports on general causation were due March 31, 2017.² (Order 1.)

² The Court defined initial reports as the reports of the parties bearing the burden of proof,

By contrast, “bellwether case-specific” discovery is discovery relating to the specific facts of an individual bellwether case. As Plaintiffs’ counsel explained to the Court, a case-specific expert could be “an anesthesiologist or an orthopedic surgeon” who opined on the specific facts of the bellwether case. (Dkt. 1437-1, Ex. B, 6/15/17 Tr. 37:24-38:17.) Deadlines for disclosure of bellwether case-specific experts have been set on a case-by-case basis.

II. THE COURT PROHIBITED SUR-REBUTTAL REPORTS.

A. The Court Specifically Barred Plaintiffs from Disclosing a Sur-rebuttal Report to Reply to Dr. Abraham.

During the general causation phase, Plaintiffs petitioned the Court to serve sur-rebuttal reports in reply to Defendants’ expert reports. The Court rejected Plaintiffs’ petition. Following Defendants’ disclosure of rebuttal reports, Plaintiffs sent a letter to the Court acknowledging that “Pretrial Order 17 prohibits Plaintiffs from serving rebuttal reports” but suggesting an amendment to the order to allow for disclosure of sur-rebuttal opinions. (Dkt. 1437-1, Ex. C.) The Court again rejected this proposal:

MAGISTRATE JUDGE NOEL: . . . Any party who wants to call an expert witness to rebut what an initial expert’s report has said needs to disclose a rebuttal expert report by the rebuttal disclosure date. ***There will be no replies to expert rebuttal reports.*** The only thing left to do after an initial report and a rebuttal report have been disclosed is to depose each of those experts.

(Dkt. 1437-1, Ex. B, 6/15/17 Tr. 47:16-48:3 (emphasis added).)

which would be Plaintiffs for all or nearly all issues. (Dkt. 1437-1, Ex. A, 9/8/16 Tr. 18:14-22.) Rebuttal reports were the reports of the parties who did not bear the burden of proof – that is, Defendants.

In response to the Court's instructions, Plaintiffs specifically requested permission to serve a sur-rebuttal to the expert report of Dr. Abraham, Defendants' CFD expert. Plaintiffs argued that Abraham had not only rebutted the report of Plaintiffs' CFD expert, Dr. Elghobashi, but also affirmatively offered his own CFD model. (*Id.* 48:10-18.) Plaintiffs indicated that they wanted to critique Abraham's CFD through a sur-rebuttal. Defendants noted that Abraham's CFD was shown to the Court and Plaintiffs during "Science Day" in May 2016 and had been posted on 3M's website afterwards.³ Plaintiffs therefore had ample notice of Abraham's CFD and an opportunity to criticize it in their initial reports. (*Id.* 49:19-25.) Judge Noel reiterated the Court's ruling that "there will be no expert sur-rebuttal reports." (*Id.* 51:7-11.)

For these reasons, Judge Schultz excluded Bushnell's improper sur-rebuttal report, concluding it "violates the discovery schedule created in Pretrial Order No. 4 and amended by Pretrial Order No. 17." (Order 3.)

B. Notwithstanding the Court's Clear Order, Plaintiffs Disclosed Bushnell to Critique Abraham's CFD.

Bushnell is an engineer who works for a distributor of CFD software. (Dkt. 1437-1, Ex. H, Bushnell Rpt. 1.) His report is a reply to Abraham's CFD studies of Bair Hugger Models 750 and 505, as Plaintiffs' counsel conceded. (Order 3.) Bushnell does not mention Plaintiff Axline or address any of the facts of her surgery. Nor does he address any of the flaws in Elghobashi's CFDs that Defendants demonstrated at the MDL *Daubert* hearing

³ Elghobashi cited Abraham's CFD as his general causation report. (Dkt. 1437-1, Ex. F, Elghobashi Rpt. 7.) Elghobashi even relied on Abraham's CFD for certain boundary conditions in his own CFD. (*Id.* 7, 32.)

and in the *Gareis* trial. His undated report is devoted entirely to purported “errors” in Abraham’s CFD models. Plaintiffs’ counsel was almost certainly referring to Bushnell’s work when they asked the Court for leave to serve a sur-rebuttal to Abraham at the June 15, 2017 status conference. Bushnell also attended Abraham’s MDL deposition a few weeks later – meaning he was likely retained in June 2017, at the time of Plaintiffs’ request – and Plaintiffs advanced several of Bushnell’s critiques at the deposition. (Dkt. 1437-1, Ex. E, Abraham Dep. 2:14 (noting attendance of Nathan Bushnell).)

In short, Bushnell’s report is both a rehash of arguments Plaintiffs have already made against Abraham, and, as Judge Schultz concluded, an obvious attempt to end-run the Court’s prohibition on sur-rebuttal reports.

Rules 16(f)(1)(C) and 37(b)(2)(A) specify sanctions for violating a Rule 26(f) scheduling order. Judge Schultz imposed the least of these sanctions – prohibiting Plaintiffs from using Bushnell’s opinions in any motion, hearing or trial. Fed. R. Civ. P. 37(b)(2)(A)(ii) (as a sanction for violating a discovery order, court may prohibit the party “from introducing designated matters in evidence”).⁴

⁴ Plaintiffs argue that Rule 37(b)(2)(A) applies only where a party has failed to make a disclosure required by the Court. They cite no case supporting this overly narrow view of the rule. Moreover, Rule 16(f) accords broad latitude to the Court to fashion “any just orders” for “fail[ure] to obey a scheduling or other pretrial order,” without any exception for harmless or substantially justified failures.

III. DAVID’S REPORT AND OPINIONS DRASTICALLY EXPAND HIS ALTERNATIVE DESIGN OPINIONS.

In March 2017, Plaintiffs disclosed David’s general causation expert report. David is a biomedical engineer. One purpose of his report was to attempt to satisfy Plaintiffs’ burden (a burden they carry under the law of nearly every state) to prove the existence of feasible safer alternative designs for the Bair Hugger system. Plaintiffs did not offer any other expert opinions on alternative design.

David’s original report opined that “the most appropriate alternative designs for operative patient warming devices are those which do not circulate air in the surgical environment.” (Dkt. 316, David Rpt. 43.) He then discussed several specific products that he asserted do not circulate air or otherwise pose a lower risk: the VitaHEAT UB3, the Berchtold TableGard, the Mistral-Air, and the Cincinnati Sub-Zero WarmAir. (*Id.* 38-42.) At David’s August 2017 deposition, Plaintiffs’ counsel asked him to identify “other design concepts which are feasible to be made without the same risk mechanism that you identified in your report.” He did not identify any other alternative designs beyond the four identified in his original report. (Dkt. 1437-1, Ex. D, David Dep. 293:5-16.)

In *Gareis*, this Court excluded David’s alternative opinions as to patient warming products other than the TableGard for reasons addressed in the briefing and at oral argument. Following the jury verdict, Plaintiffs greatly expanded David’s opinion on the range of “alternative” warming products.

David’s supplemental report – disclosed 17 months after his original report – describes seven additional products and warming methods he maintains are safer

alternatives to the Bair Hugger system. (Dkt. 1437-1, Ex. E, David Supp. 1.) As David's report makes clear, all the publications he relies upon were available when he disclosed his original report in March 2017:

Newly Disclosed “Alternative Design”	Date of David's Support
Kanmed WarmCloud, which “[m]uch like the Berchtold Tablegard discussed in my initial report . . . uses forced-air to achieve underbody heating without exhausting air around the operating site.”	May 2008 study published in the <i>European Journal of Anaesthesiology</i> . (<i>Id.</i> & n.3)
Inditherm, a conductive mattress.	August 2011 guidance document published by the National Institute for Health and Clinical Excellence. (<i>Id.</i> 1-2 & n.5)
LMA PerfecTemp, an “underbody resistive warming system.”	June 2011 study published in <i>Anesthesia & Analgesia</i> . (<i>Id.</i> 2 & n.11.)
Barrier Easy Warm, a “disposable, active self-warming blanket.”	December 2013 poster presentation on trial of this product. (<i>Id.</i> 3 & n.17.)
Reflective blankets.	July 2016 study published in the <i>Journal of Arthroplasty</i> . (<i>Id.</i> n.21.)
Cotton blankets.	November 2008 study published in the <i>British Journal of Anaesthesia</i> . (<i>Id.</i> 3-4 & n.25.)
Prewarming.	2001 study published in the <i>Lancet</i> . (<i>Id.</i> 4 & n.26.)

As Judge Schultz concluded, David could have given these opinions in his original general causation report. (Order 5; 9/6/18 Tr. 57:13-20.) There also is nothing case-specific about David's report. He makes no reference to Ms. Axline or her surgery.

ARGUMENT

"The standard of review applicable to an appeal of a Magistrate Judge's order on nondispositive pretrial matters is extremely deferential." *Mayo Clinic v. U.S.*, No. 16-cv-3113 (JNE/KMM), 2018 WL 118373, *1 (D. Minn. Mar. 7, 2018) (quotation omitted). This Court should reverse such an order only if it is clearly erroneous or contrary to law. *Id.* Here, Judge Schultz's order was well supported by the evidence and the Court's prior orders, and correctly applied Rule 16, Rule 37, and controlling case law.

I. JUDGE SCHULTZ CORRECTLY BARRED PLAINTIFFS FROM USING BUSHNELL'S DISALLOWED SUR-REBUTTAL OPINIONS.

Judge Schultz correctly barred Bushnell's report and opinions because they violated the Court's express prohibition against sur-rebuttal reports. As Judge Schultz noted, Plaintiffs concede Bushnell's report replies to Abraham's rebuttal report. (Order 3.) Plaintiffs specifically asked the Court on June 15, 2017 to be allowed an expert sur-rebuttal to critique Abraham's CFD. The Court said no. (*Id.* 4.) Rule 26(a)(2)(D) supports the Court's ruling by providing for disclosure of initial and rebuttal reports but not sur-rebuttal reports. Moreover, there was no surprise to Plaintiffs that Abraham would rely on his own CFD in rebutting Elghobashi. Abraham's CFD was shown at "Science Day" in May 2016, was posted on 3M's website shortly thereafter, and was even relied upon by Elghobashi in choosing inputs for his own CFD. Plaintiffs made a strategic decision not to critique

Abraham's CFD in their original expert reports, and now they must live with it. *See Trost v. Trek Bicycle Corp.*, 162 F.3d 1004, 1008-09 (8th Cir. 1998) (noting that "[i]t is risky for a [party bearing the burden of proof] to sit back and wait to see what a defense expert might say before seeking an expert report" and finding no abuse of discretion in exclusion of plaintiff's belatedly disclosed expert opinion).

Judge Schultz also properly rejected Plaintiffs' argument that the Court's expert deadlines do not apply to Bushnell because he is an "impeachment" expert who will be called at trial only to rebut the opinions of Abraham. There is no such thing as an "impeachment" expert under the Federal Rules. The case Plaintiffs rely upon, *Wegener v. Johnson*, 527 F.3d 687, 690-91 (8th Cir. 2008), "is clear that any expert opinion that may be used to rebut another expert must obey applicable scheduling orders." (Order 4; *see also* 9/6/18 Tr. 55:24-55:8 (noting that allowing additional disclosure of general causation "impeachment" experts "would eviscerate the limit that the Court placed on an initial round and then a rebuttal round and no sur-rebuttals.")).

Exclusion under Rules 16(f)(1)(C) and 37(b)(2)(A)(ii) does not require any demonstration of prejudice.⁵ *Cf. Comstock v. UPS Ground Freight, Inc.*, 775 F.3d 990, 992 (8th Cir. 2014) (requiring demonstration of prejudice only where sanction sought under

⁵ Excluding David's new opinions is not "tantamount to dismissal" of Plaintiffs' design defect claims, as Plaintiffs argue. Plaintiffs withstood summary judgment and proceeded to trial in *Gareis* based on David's original opinions. Plaintiffs also cite no case holding that exclusion of a belatedly disclosed expert opinion requires proof of prejudice. Any such holding would be contrary to *Comstock* and Eighth Circuit law. Moreover, Defendants would be unfairly prejudiced in their defense if they could not conduct discovery on the studies and devices David discusses for the first time.

Rule 37(b)(2) is dismissal of the case). In any event, Defendants *were* prejudiced and would be prejudiced further if Plaintiffs' objection is sustained. Defendants were forced to have Abraham prepare a sur-sur-rebuttal to Bushnell's critique and would be forced to incur the additional time and expense of deposing Bushnell. Moreover, the Court should not have to consider a *Daubert* motion on a purely rebuttal expert whose report should never have been served in the first place. For this additional reason, Plaintiffs' objection should be overruled.

II. JUDGE SCHULTZ PROPERLY BARRED DAVID'S BOLSTERING OF HIS ALTERNATIVE DESIGN OPINIONS.

A. David Improperly Adds New Opinions and Goes Far Beyond Permissible Supplementation under Rule 26(e).

Judge Schultz also correctly barred Plaintiffs from using David's new alternative design opinions in any motion, hearing, or trial pursuant to Rule 37(c). As Judge Schultz concluded, David's new opinions go beyond proper supplementation under Rule 26(e). (Order 4-5.)

Rule 26(e) requires a party to supplement its expert disclosures if "the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." But "[a] supplemental expert report that states additional opinions or rationales or seeks to 'strengthen' or 'deepen' opinions expressed in the original expert report exceeds the bounds of permissible supplementation and is subject to exclusion under Rule 37(c)." *Cook v. Rockwell Corp.*, 580 F. Supp. 2d 1071, 1169 (D. Colo. 2006). "To rule otherwise would create a system where preliminary

[expert] reports could be followed by supplementary reports and there would be no finality to expert reports, as each side, in order to buttress its case or position, could ‘supplement’ existing reports and modify opinions previously given.” *Id.* Most courts in this District and elsewhere take the same view. *See, e.g., 3M Innovative Props. Co. v. Dupont Dow Elastomers, LLC*, No. 03-3364, 2005 WL 6007042, *5 (D. Minn. Aug. 29, 2005) (“Because the amendments . . . were served long after discovery closed, they are time-barred, and DDE’s offer of a second deposition of Balke is inapposite. Discovery deadlines are meaningful, and this Court will not allow a party to unilaterally choose to extend them by over a year.”); *Medtronic Vascular, Inc. v. Abbott Cardiovascular Sys., Inc.*, 2008 WL 4601038, *1 (N.D. Cal. Oct. 15, 2008) (“A party may not rely on Rule 26(e)(1) as a way to remedy a deficient expert report or as a means of getting in, in effect, a brand new report.”). MDL courts also have taken the same approach. *See, e.g., Robbins v. Boston Sci. Corp.*, 2016 WL 3189248, *11 (S.D. W.Va. June 7, 2016); *In re Bear Stearns Cos., Inc. Secs. Litig.*, 263 F. Supp. 3d 446, 452-53 (S.D.N.Y. 2017). Plaintiffs fail to identify any case from this District or the Eighth Circuit rejecting this line of authority.

As Judge Schultz concluded, the logic of this case authority applies here. (Order 5; 9/6/18 Tr. 59:10-16.) David is not merely correcting a point of incompleteness (by discussing additional research supporting his opinions), fixing an inaccuracy, or addressing newly available information. All seven of the new “alternatives” were available at the time of his original report, and all the studies he cites in support of them were available before he sat for his deposition. These seven additions to David’s list of “safer alternative” products represent a major new substantive disclosure, well beyond what Rule 26(e)

permits. *See, e.g., Robbins*, 2016 WL 3189248, *11 (excluding supplemental expert report under Rule 37(c)(1) that “provides new opinions based on additional pathological examinations, though the relevant samples appear to have been excised in early 2013, well before the deadline for expert disclosures”).

Defendants recognize that, in serial litigation like this, expert opinions may evolve somewhat from one case to the next as the disputed scientific issues achieve greater definition. Experts may address previously undisclosed studies that provide support for (or contradict) the opinions expressed in their original reports. Such supplementation is permissible, in Defendants’ view, if the new material falls within the parameters of the expert’s originally disclosed opinions.⁶ It may also become necessary to disclose additional experts to “share the burden” of working up hundreds of cases in a protracted MDL. David’s supplemental report cannot be justified on either basis. Adding seven new warming modalities to his original list of “safer alternatives” – all of which were available at the time of David’s MDL report – opens entirely new areas that cannot be adequately addressed by another deposition.

B. Plaintiffs Cannot Prove Their Late Disclosure of David’s Opinions Is Harmless.

Judge Schultz also correctly concluded that Plaintiffs did not meet their burden to show their belated disclosure of David’s seven additional designs is harmless. *See Transam. v. Lincoln Nat. Life Ins.*, 592 F. Supp. 2d 1087, 1094 (N.D. Iowa 2008) (burden

⁶ Despite repeatedly alleging that Defendants have also improperly supplemented their general causation opinions, Plaintiffs have never identified any specific example to Defendants, much less to the Court.

is on the proponent of the late-disclosed evidence or information to show that the late disclosure was substantially justified or harmless). Defendants were forced to incur the cost of having their own experts respond to David's new opinions. Defendants also have had no opportunity to conduct fact discovery on any of the newly identified products or warming methods. (Order 5 ("Defendants would be prejudiced by the admission of David's new report, as they would need to investigate each of the seven additional feasible alternatives.")) That 3M has some internal research on a few of these devices is hardly a substitute for discovery of the manufacturers themselves. Moreover, Defendants have had no opportunity to depose the researchers who conducted the studies David cites. Much of the key evidence in this litigation comes from document discovery and depositions of the authors of significant studies.

Judge Schultz further concluded that conducting this additional discovery "would be a tall task in the shadow of the looming *Axline* trial." (Order 5.) Even if the *Axline* trial does not proceed on December 3 (as now seems likely), the prejudice to Defendants of undertaking costly general causation discovery remains. Accepting Plaintiffs' position that the parties may disclose new general causation expert opinions at any time will inevitably result in extensive, ongoing new expert disclosures by *both sides* (new initial reports, new rebuttal reports, and new depositions), imperiling the ability of the parties and the Court to focus on working up bellwether cases for trial.

C. The New Expert Opinions Also Are Not Substantially Justified by the Court's Rulings in *Gareis*.

Finally, Judge Schultz correctly concluded that Plaintiffs did not demonstrate that David's belated disclosure is substantially justified. (Order 5.) *See Transam.*, 592 F. Supp. 2d at 1094 (burden is on proponent of the late-disclosed evidence or information to show that the late disclosure was substantially justified or harmless).

Plaintiffs argue that David's supplement is justified by this Court's decision in *Gareis* to allow Plaintiffs to present the TableGard as an alternative design at trial. According to Plaintiffs, David did not address conductive systems in his original report because the Court had ordered that conductive systems could not legally qualify as alternative designs. He is now addressing conductive systems. (Dkt. 1437-1, Ex. I, 8/16/18 Tr. 23:2-9.) Plaintiffs are incorrect.

First, David *did* address conductive patient warming systems in his original report. He addressed the VitaHEAT UB3, the same product that had been the subject of the Court's order. (Dkt. 316, David Rpt. 38-39.) A few weeks earlier, Judge Noel had granted a protective order to VitaHEAT, concluding that the UB3 "is not an alternative design, but an entirely different product. . . . The Bair Hugger system could not be modified to become a conductive patient warming device." (Dkt. 249 at 3.) The Court affirmed. (Dkt. 304.) Plaintiffs' objection to Judge Noel's order was still pending at the time David's original report was disclosed, and David still addressed the VitaHEAT UB3 and conductive warming. David's original report also, of course, addressed the TableGard, which warms

patients conductively. (Dkt. 316, David Rpt. 39 (David stated the TableGard “uses a closed recirculation system to provide conductive warming”).)

Second, as Judge Schultz noted, the Court did not reverse the VitaHEAT order in *Gareis*. At most, the *Gareis* order modified the VitaHEAT order through its summary judgment decision in *Gareis*. The basis for Judge Noel’s ruling, which the Court affirmed, was Plaintiffs’ failure to demonstrate that the Bair Hugger system could be modified to incorporate the conductive warming technology of the VitaHEAT UB3, which is essentially an electric mattress. (Dkt. 249 at 3.) In *Gareis*, the Plaintiffs presented a triable question of whether the Bair Hugger system could be modified to incorporate the TableGard’s technology. The Court did not thereby reopen the door to the VitaHEAT UB3 or any other electric-mattress system as an alternative design – systems that are so different that their technology cannot be incorporated into the Bair Hugger system. (Order 17; 9/6/18 Tr. 57:20-59:2.)

CONCLUSION

For the foregoing reasons, the Court should overrule Plaintiffs’ objection.

Dated: October 18, 2018

Respectfully submitted,

s/Benjamin W. Hulse

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